IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

DIAGNOSTIC DEVICES, INC. **Plaintiff,** **v.** **PHARMA SUPPLY, INC., et al.,** **Defendants.**	**CASE NO.: 3:08-cv-00149-MOC-DCK**
DIAGNOSTIC DEVICES, INC., **Plaintiff,** **v.** **TAIDOC TECHNOLOGY CORPORATION,** **Defendant.**	**MEMORANDUM IN SUPPORT OF PLAINTIFF AND COUNTERCLAIM DEFENDANTS' MOTION IN LIMINE NO. 1 (PRECLUDING ANY EVIDENCE OR ARGUMENT SUGGESTING DDI WAS NOT IN COMPLIANCE WITH FDA REQUIREMENTS)**
TAIDOC TECHNOLOGY CORPORATION, **Counterclaimant,** **v.** **DIAGNOSTIC DEVICES, INC., RICHARD ADMANI, an individual, RAMZI ABULHAJ, an individual, and PRODIGY DIABETES CARE, LLC,** **Counterclaim Defendants.**	

Plaintiff Diagnostic Devices, Inc. ("DDI") and Counterclaim Defendants DDI, Richard Admani, Ramzi Abulhaj and Prodigy Diabetes Care, LLC ("PDC") (collectively, "Plaintiff") respectfully move the Court to exclude all evidence and argument that DDI did not comply with

the Food and Drug Administration's ("FDA") 510(k) premarket notification requirements or that DDI defrauded the FDA during its investigations of DDI's business operations.

Introduction

Despite the fact that the FDA investigated DDI's business twice and did not find any failure by DDI to comply with its regulations, Pharma Supply, Inc. ("Pharma") and TaiDoc Technology Corp. ("TaiDoc") have made clear that they will attempt to introduce evidence and make arguments at trial that DDI was not in compliance with FDA requirements during the relevant time period. Pharma's trial exhibit list includes nineteen exhibits titled "Evidence of DDI's Violation of FDA Regulations." In addition, TaiDoc and Pharma's joint motion for summary judgment argues that "there is still no 510k review or clearance given for any of the meters and strips that 'DDI' sells" and further indicated that, at trial, Pharma or TaiDoc will attempt to persuade the jury that DDI defrauded the FDA during their investigation of DDI. [PD178 at 10][1] Pursuant to established case law, however, a jury cannot second guess the FDA's determinations and parties are precluded from suggesting that the FDA's approval is based upon another party's fraud.

Because the FDA did not find that DDI failed to comply with the 510(k) premarket notification requirements, any argument or evidence to the contrary would be irrelevant, unfairly prejudicial to DDI, confuse the issues, and mislead the jury. Accordingly, Plaintiff's Motion in Limine Number 1 should be granted.

[1] "PD_" will refer to documents electronically filed in the 3:08-CV-00149 case against Pharma.

Argument

"Irrelevant evidence is not admissible." Fed. R. Evid. 402. "Evidence is relevant if: (a) it has a tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401.

Relevant evidence may also be excluded "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. The Fourth Circuit regularly affirms a district court's exclusion of evidence that could inject collateral issues and mislead the jury from the real issues in the case. E.g., Lewis v. Sentara Alternative Delivery Sys., 1998 U.S. App. LEXIS 3656, at *8 (4th Cir. Mar. 2, 1998) ("Excluding testimony under Rule 403 to avoid litigating collateral matters was not an abuse of discretion"); United States v. Grossman, 400 F.3d 212, 218-19 (4th Cir. 2004) ("The trial judge was correct in finding that the insignificant probative value of this evidence was easily outweighed by a desire to avoid confusing and distracting the jury"); see also United States v. Rand, 2011 WL 4914952, at *5 (W.D.N.C. Oct. 17, 2011) (granting motion in limine to preclude evidence of Wachovia's loss because such evidence "would confuse the issues, mislead the jury and result in needless presentation of cumulative evidence").

I. PHARMA AND TAIDOC CANNOT SECOND GUESS THE FDA'S DETERMINATION THAT DDI WAS IN COMPLIANCE WITH ITS REGULATIONS, THEREFORE ANY SUCH EVIDENCE OR ARGUMENT IS IRRELEVANT.

Applying 21 U.S.C. § 337(a) and Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 3431 (2001) the Court in PhotoMedex, Inc. v. Irwin, 601 F.3d 919 (9th Cir. 2010), held that a party cannot litigate any "alleged underlying [Food, Drug and Cosmetic Act] violation" in furtherance of a claim against a device manufacturer "in a circumstance where the FDA has not

itself concluded there was such a violation." Id. at 924 (affirming summary judgment against plaintiffs on claims that a competitor violated the 510(k) requirements). Indeed, the Ninth Circuit explicitly held in PhotoMedex that a party cannot succeed in "requir[ing] the finder of fact to make a decision that the FDA itself did not make." Id. at 930.

Here, there is no evidence of a determination by the FDA that DDI was not in compliance with the 510(k) premarket notification requirements to market and sell blood glucose meters and strips. To the contrary, despite a formal complaint by TaiDoc that DDI was producing counterfeit test strips, the FDA found this not to be the case after conducting a six-day onsite investigation. [PD195, paras. 15-18; PD179-52 at 1-2 ("EIR")] Indeed, in August 2009, the FDA determined that DDI was in compliance with its 510(k) requirements and was not counterfeiting or importing fake glucose test strips. [Id.] Even after this determination, the FDA conducted a second audit of DDI in May 2011 and again found no problem with DDI's devices or its compliance with the 510(k) requirements. [PD195, paras. 21, 23] Accordingly, the FDA has repeatedly determined that DDI is in compliance with the 510(k) premarket notification process and related requirements for its products. As such, the Defendants may not collaterally attack the FDA's determination.

The law does not permit TaiDoc and Pharma to use a jury to "usurp the FDA's prerogative to enforce the FDCA" and to "make a decision that FDA chose not to make." PhotoMedex, at 928-29; see also Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993) (holding a party cannot use the court "as a vehicle by which to enforce the Food, Drug, and Cosmetic Act ("FDCA") and the regulations").

Because the law does not allow a party to second guess the determinations of the FDA, any evidence submitted by TaiDoc and Pharma suggesting that DDI did not comply with the

510(k) requirements would be irrelevant as it would not have a "tendency to make the existence of any fact that is of consequence to the determination of the action more or less probable." Accordingly, it should be excluded under Rule 401. See Garraghty v. Jordan, 830 F.2d 1295, 1298 (4th Cir. 1987) ("The evidence excluded by the court on the defendants' motion in limine was clearly irrelevant as well as confusing").

Further, where the FDA conducted an investigation and failed to find that DDI was not in compliance with the 510(k) premarket notification requirements, any relevance of unsupported evidence to the contrary is marginal at best. Allowing such evidence or argument to second guess the FDA's determination would inject unfair prejudice against Plaintiff, serve to confuse the issues, and likely would mislead the jury. Fed. R. Evid. 403. Indeed, the only effect of allowing this type of evidence or argument is to mislead the jury away from the clear facts, confuse the issues, and invite the jury to make determinations that the FDA affirmatively chose not to make. For these reasons, the Court should grant Plaintiff's motion and exclude any such evidence or argument during the trial.

II. PHARMA AND TAIDOC CANNOT PRESENT EVIDENCE OR ARGUMENT THAT DDI DEFRAUDED THE FDA.

This Court should not entertain the introduction of any evidence or argument regarding that DDI somehow misled or committed fraud on the FDA because the United States Supreme Court's decision in Buckman expressly precludes private litigants from pursuing any claims premised on such allegations. Id. at 353. In Buckman, the plaintiffs alleged that they suffered injuries from a medical device cleared by the FDA as a result of defendant's fraudulent misrepresentations to the FDA—"[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." Id. at 343. In rejecting such a claim, the Court unanimously concluded that "the federal statutory scheme amply

empowers the FDA to punish and deter fraud against the Agency" and that authorizing private claims premised on an alleged failure to comply with FDA requirements "would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." Id. at 348, 353.

Buckman not only preempts affirmative claims by private litigants premised on fraud on the FDA, but also precludes any evidence or argument at trial suggesting that a party defrauded the FDA. Applying Buckman, the federal district court for the Northern District of Ohio granted a motion in limine precluding evidence for this precise reason. Bouchard v. American Home Prods. Corp., 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002) (precluding evidence of fraud on the FDA at trial). Concerned that the plaintiff would attempt to introduce evidence and argue "that [defendant] mislead the FDA or failed to follow FDA regulations," defendant filed a motion in limine to preclude such evidence and argument by plaintiff. Id. at 811. In granting the motion in limine, the Court adhered to Buckman and "determined that private actions premised on fraud on the FDA are not permitted" and held that "[e]vidence will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA." Id. at 812

Pursuant to Buckman, Bouchard, and PhotoMedex, TaiDoc and Pharma may not introduce evidence or argument that DDI allegedly engaged in fraud with respect to its dealings with the FDA, and likewise, cannot ask the jury to second guess the FDA's prior determinations. Buckman, 531 U.S. at 350 (holding that allowing private litigants to pursue claims premised on allegations of fraud on the FDA would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives").

As demonstrated, the law does not allow a party to base a claim on allegations that a party committed fraud on the FDA. As such, any evidence submitted by TaiDoc and Pharma to suggest that DDI committed fraud or misled the FDA would not have a "tendency to make the existence of any fact that is of consequence to the determination of the action more or less probable." Accordingly, it should be excluded under Rule 401. See Garraghty, 830 F.2d at 1298 ("The evidence excluded by the court on defendants' motion in limine was clearly irrelevant as well as confusing").

Further, even if the Court found evidence of fraud on the FDA to be marginally relevant—which it is not—it should still be excluded because introduction of such evidence would inject unfair prejudice against Plaintiff, serve to confuse the issues, and likely would mislead the jury. Fed. R. Evid. 403.[2]

Relief Requested

For the foregoing reasons, Plaintiff respectfully requests that this Court exclude any evidence or argument suggesting that DDI was not in compliance with FDA regulations or that DDI misled or defrauded the FDA.

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[2] This Court should also preclude TaiDoc and Pharma from suggesting that DDI or other entities owned by Ramzi and Rick, such as DispoMed, did not comply with the 510(k) premarket notification or approval requirements for products that are not subject to such FDA requirements. For example, during the deposition of Rick Admani, Pharma asked if "disposable devices that were sold by DispoMed [were] FDA approved" and attempted to restrict Rick's answer to "yes" or "no" despite that these disposable devices were manufactured in China and sold in Latin America and the Middle East, and therefore, not subject to FDA requirements. [Admani Dep. 26:3-8, 29:11-30:1] See 21 U.S.C. § 381(a) (requiring foreign manufacturers to register their establishments if they import medical devices to the United States); 21 C.F.R. § 807.81(a) (requiring registered establishments to obtain premarket notification). Any attempt by Pharma or TaiDoc to make similar suggestions through questioning or argument at trial would be wholly irrelevant, unduly prejudicial, and confusing to the jury. Garraghty, 830 F.2d at 1298 (granting motion in limine to exclude evidence that was irrelevant and confusing); Rand, 2011 WL 4914952, at *5 (granting motion in limine to preclude evidence that would mislead the jury and confuse the issues).

This 7th day of March, 2012.

JAMES, McELROY & DIEHL, P.A.

s/ Richard B. Fennell
Richard B. Fennell (NC Bar No. 17398)
Jared E. Gardner (NC Bar No. 28275)
Adam L. Ross (NC Bar No. 31766)
Jon P. Carroll (NC Bar No. 33850)
600 South College Street
Charlotte, North Carolina 28202
Telephone: (704) 372-9870
Facsimile: (704) 333-5508
E-mail: rfennell@jmdlaw.com
jgardner@jmdlaw.com
aross@jmdlaw.com
jcarroll@jmdlaw.com

Lawrence G. Scarborough (Admitted Pro Hac Vice)
J. Alex Grimsley (Admitted Pro Hac Vice)
BRYAN CAVE LLP
Two North Central Avenue, Suite 2200
Phoenix, Arizona 85004-4406
Telephone: (602) 364-7000
Facsimile: (602) 364-7070
E-mail: lgscarborough@bryancave.com
jagrimsley@bryancave.com

Attorneys for Plaintiff and Counterclaim Defendants

CERTIFICATE OF SERVICE

The undersigned hereby certifies that this **MEMORANDUM IN SUPPORT OF PLAINTIFF AND COUNTERCLAIM DEFENDANTS' MOTION IN LIMINE NO. 1 (PRECLUDING ANY EVIDENCE OR ARGUMENT SUGGESTING DDI WAS NOT IN COMPLIANCE WITH FDA REQUIREMENTS)** was served on all parties to this action via the Court's CM/ECF system as follows:

Robert L. Burchette
JOHNSTON, ALLISON & HORD, P.A.
1065 East Morehead Street
Charlotte, North Carolina 28204
rburchette@jahlaw.com

Mitchell A. Stein
STEIN LAW, P.C.
24 Woodbine Avenue, Suite 4
Northport, New York 11768
mitch@kingofip.com

Attorneys for Defendant Pharma Supply, Inc. National Hope Respiratory Service, Inc., d/b/a Diabetic Support Program, and Frank Suess

Bradley Robert Slenn
Frank A. Mazzeo
RYDER, LU, MAZZEO & KONIECZNY, LLC
808 Bethlehem Pike, Suite 200
Colmar, Pennsylvania 18915
bslenn@ryderlu.com
fmazzeo@ryderlu.com

Kao H. Lu
RYDER, LU, MAZZEO & KONIECZNY, LLC
1425 East Darby Road
Havertown, Pennsylvania 19083
klu@ryderlu.com

Daniel Bishop
BISHOP, CAPITANO & MOSS, P.A.
4521 Sharon Road, Suite 350
Charlotte, North Carolina 28211
dbishop@bcandm.com

Attorneys for Defendant and Counterclaimant Taidoc Technology Corporation

This 7th day of March, 2012.

s/ Jon Paul Carroll